Advances in Human Health Risk Assessment: Use of Human Data

John Vandenberg
Associate Director (acting)
ORD/NCEA
(202) 564 3407
vandenberg.john@epa.gov

Key Words: advances human health risk assessment

Risk management by EPA, State, Local and Tribal authorities is based on an understanding of the potential health risks of environmental pollution and the benefits to public health and society from management efforts. Estimation of health risks usually entails evaluation of pertinent health data from epidemiological and clinical studies using human subjects and from extrapolation of data from animal toxicology and in vitro studies. The use of human subjects requires utmost care be taken to ensure the ethical and scientific appropriateness of the research. This session explores advances in the ethics of EPA's use of human data and advances in application of human data to address Agency needs. The desired outcome is an appreciation for the challenges and opportunities faced by EPA research and regulatory programs related to use of human subjects data.

Session structure:
Introduction (15 minutes): EPA's use of Human Subjects Research: Peter Preuss, PhD, EPA Human Subjects Research Review Official, is Director of the National Center for Environmental Assessment and has a long history as EPA's designated HSRRO.

Ethics of Human Research (35 minutes): James F. Childress, PhD, John Allen Hollingsworth Professor of Ethics, Professor of Medical Education, and Director, Institute of Practical Ethics and Public Life, University of Virginia, Charlottesville, VA, is co-chair of the NAS committee on the Use of Third Party Toxicity Research with Human Research Participants Ethicist from the NAS report on Intentional Human Dosing Studies for EPA Regulatory Purposes. He would speak to the issues and conclusions developed by the NAS committee, whose report was released on February 19, 2004.

An Illustration of the Value of Ethically Derived Human Data (30 minutes): William McDonnell, MD, PhD, NHEERL HSRRO and NHEERL principal investigator, has conducted and participated in the study of hundreds of individuals as a key leader in EPA's research to evaluate human response to controlled and environmental exposures to airborne pollutants at EPA's Human Studies Division. His approaches have targeted key questions affecting regulatory decision making for ozone pollution, and his studies were central to the decision in 1997 to significantly revise the ozone ambient air quality standard to protect public health with an adequate margin of safety. He will provide insights on the value of human clinical research and its coupling with epidemiological research through state-of-the-art modeling to support decision making.

Extending Human Data to Improve Interpretation of Animal Toxicology Data (30 minutes) ([Alternate: Perchlorate Risk Assessment: Application of Human Data by Annie Jarabek]): Robert Devlin, PhD, Chief, Clinical Research Branch, EPA, has been a leader of EPA's single largest health research program, dealing with particulate matter, and has had responsibility to develop and implement a research program to understand the role of PM on health. His human subjects' research has been closely coupled with animal toxicology research to address critical questions of biological plausibility and demonstrates the value of leveraging human and animal toxicology research to support decision making. He will provide a framework for human and animal toxicology in in vivo and in vitro research and EPA's successful efforts to address vexing questions affecting national air quality decision making.

Future Advances and Challenges in Human Studies: The Human Genome (35 minutes): Speaker to be announced. A prominent speaker involved in computational toxicology and, in particular, the recent advances in genomic, proteomic, and metabolomic approaches will be recruited to provide insights on future directions and opportunities for utilizing the human genome, as well as challenges faced in using such information in health risk assessment.

Question and Answer period/wrap up: Speakers serve as panelists (20 minutes).